RESPONSE

I. Status of the Claims

Prior to the Action, claims 1-19, 23, 51, 52 and 93-122 were pending and have been examined. Presently, claims 1, 9-12, 23, 94, 96-99, 102, 107, 115, 120 and 122 have been amended, without prejudice or disclaimer. Claims 93, 95, 100, 101, 103, 104, 108-110, 113, 114, 118 and 119 have been cancelled, without prejudice or disclaimer. No claims have been added.

Claims 1-19, 23, 51, 52, 94, 96-99, 102, 105-107, 111, 112, 115-117 and 120-122 are therefore in the case. According to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

II. Support for the Claims

Support for the revised claims exists throughout the specification and claims of the original and parent applications and, particularly, in the pending claims.

Claim 1 has been revised to define the claimed antibody as recited in claims 9 or 10, in the alternative, and to recite the ELISA of claim 101. Support exists at least in claims 9, 10 and 101 (see also, specification at Example IV-D). In addition, "monoclonal" has been deleted, which has particular support in claim 1 as filed.

Claims 9-11 have each been revised to succinctly refer to "said" ELISA of claim 1, which provides the required support, as set forth above.

Claim 12 has been revised to recite a "monoclonal" antibody, which has particular support in claim 12 as filed.

Claim 23 has been revised to succinctly refer to the antibody as defined in claim 1, which provides the required support, as set forth above.

Claims 94, 97 and 98 have each been revised as set forth above for claim 1, and are thus supported likewise.

Claim 96 has been revised to succinctly recite an antibody as defined in claim 1, which provides the required support, as set forth above.

Claim 99 has been revised to succinctly refer to the antibody as defined in claim 97, which provides the required support, as set forth above.

Claim 102 has been revised to depend from claim 1.

Claim 107 has been revised to recite the ELISA of earlier claims, *e.g.*, claim 101, and is supported by claim 101 and others (see also, specification at Example IV-D).

Claim 115 has been revised to depend from claim 97.

Claim 120 has been revised to depend from claim 98.

Finally, claim 122 has been revised to recite hybridoma ATCC PTA 4545, which is supported at least by claims 117 and 121.

It will therefore be understood that no new matter is included within any of the amended claims.

III. Rejections Overcome and Response Summary

In the second Action, all previous clarity rejections under 35 U.S.C. § 112, second paragraph have been withdrawn, and the previous enablement rejection under 35 U.S.C. § 112, first paragraph has been withdrawn. The previous anticipation rejection under 35 U.S.C. § 102(b) has been withdrawn, although applied to other claims. Applicants appreciate the withdrawal of these rejections.

Although most claims are newly rejected, Applicants appreciate the examiner's guidance on overcoming the present rejections, both as set forth in this Action and in co-pending applications in which the same issues were present and/or rejections overcome.

Applicants appreciate the indication that claims 9, 10, 11 and 107 are free from the four anticipation rejections under 35 U.S.C. § 102(b), and that no claims have been rejected as obvious under 35 U.S.C. § 103(a). In light of this guidance, Applicants elect to place all claims in condition for allowance using the language already found to be novel and non-obvious. Accordingly, claims 1, 94, 97 and 98 have each been revised to recite the language of claims 9 and 10, in the alternative, and claim 107 has been maintained (**Sections IX, X** and **XI**).

The new matter rejection under 35 U.S.C. § 112, first paragraph is overcome by Applicants' response at **Section V**, which includes evidence of allowance, allowability and other positive decisions from Examiner Goddard in three co-pending applications in which the same issues were present and/or rejections overcome.

The written description rejection under 35 U.S.C. § 112, first paragraph and the rejection under 35 U.S.C. § 101 are overcome by Applicants' response **Sections VI** and **VII**.

The provisional obviousness-type double patenting rejections are overcome by the enclosed terminal disclaimer (**Section XII**).

All claims are therefore in condition for allowance, based upon the claims not subject to rejection and the present response, including evidence of the examiner's allowance and positive decisions in co-pending applications with the same issues.

IV. Objection to the Specification

The second Action objects to the specification, alleging that the amendments to the specification submitted in Applicants' last response introduced new matter into the disclosure in

regard to the serum-dependence of antibodies other than the 3G4 antibody (second Action at pages 2-3).

The same objection was made in co-pending application Serial No. 10/642,118 ("the '118 application"; Attorney Docket No. 4001.003085), in which the same amendments to the specification were earlier submitted. Communications and interviews in the '118 application, which was also examined by Examiner Goddard, resulted in definite agreement on further minor changes to the specification. A Notice of Allowance was mailed in the '118 application on May 21, 2007, and the patent will issue on July 24, 2007 (**Exhibit A**). Each of the agreed changes to the specification in the '118 application has been incorporated in the concurrent amendments to the present specification. As summarized below, each of the present amendments to the specification has thus been approved by the Office.

A telephone interview in the '118 application was held between Examiner Goddard, SPE Shanon Foley, Shelley Fussey and Jennifer Chheda on March 05, 2007. Prior to the interview, Applicants submitted a draft of the proposed amendments to the specification for review by Examiner Goddard and SPE Foley. During the telephone interview of March 05, 2007, SPE Foley indicated that, apart from one outstanding question, the current amendments to the specification are consistent with the original disclosure and therefore do not introduce new matter into the specification.

The one remaining question concerned the amendment to Table 2 of the specification to characterize the 3B10 antibody as being serum-dependent. Applicants indicated that data could be provided for the record to demonstrate that binding of the 3B10 antibody to PS is serum-dependent. SPE Foley indicated that, upon submission of such data for 3B10, the amendments to Table 2 of the specification would be entered as proper.

The text of the amendments to the specification now formally submitted in the present application is the same as the text of the amendments agreed for entry in the allowed, '118 application. The data regarding the serum-dependence of the 3B10 antibody are provided herewith in the form of the Second Declaration of Philip E. Thorpe under 37 C.F.R. § 1.132 ("the second Thorpe Declaration"). In particular, the second Thorpe Declaration provides data from ELISA assays conducted in the presence and absence of serum (second Thorpe declaration throughout, *e.g.*, paragraphs 10-13; Exhibit B).

Therefore, and as agreed in the allowed, '118 application, the earlier amendment to Table 2 of the specification, designating the 3B10 antibody as being serum-dependent, is also consistent with the original disclosure and thus does not introduce new matter into the specification.

The objection to the specification is thus overcome and should be withdrawn.

V. New Matter Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-19, 23, 51, 52, 93-104, 107-110, 113-115, 118-120 and 122 are first rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description support in the specification and thus constituting new matter. Although Applicants respectfully traverse, the rejection is overcome.

Claims 105, 106, 111, 112, 116, 117 and 121, drawn to the deposited 3G4 antibody, and the corresponding compositions, pharmaceuticals and hybridomas, are free from this ground of rejection. Applicants respectfully traverse as to the remaining claims, and the rejection is overcome according to the reasoning and evidence below and in light of the decisions of the Office in the co-pending applications.

As set forth in the second Action at pages 3-4, the present rejection is applied to the *combination* of claims reciting an antibody that effectively competes with the deposited 3G4 antibody for binding to phosphatidylserine (PS) with claims reciting an antibody that binds to PS in combination with a protein cofactor.

As claims 100, 108, 113 and 118, the only claims reciting antibody binding in combination with a protein cofactor, have been canceled without prejudice or disclaimer, the complained of "combination" of claim language no longer exists and the rejection is thus overcome.

As noted by Examiner Goddard and SPE Foley in co-pending applications in which this same issue was raised, in addition to disclosing the deposited 3G4 antibody, the specification as filed also clearly disclosed antibodies that compete with 3G4 for binding to PS as determined in the disclosed ELISA. For example, see specification at pages 6-16, *e.g.*, page 6, lines 26-29, page 8, lines 22-24, page 12, lines 7-8, and at Example IV. As the disclosed ELISA was recited in claims 101, 103, 109, 114 and 119, and further defined in claims 102, 104, 110, 115 and 120, each of these claims are further distanced from the present rejection.

Indeed, in the '118 application discussed above, the same ELISA claims have already been allowed as dependent claims that further limit composition claims in which the antibody is defined in terms of its CDR sequences (see, allowed claims 6, 7, 20 and 21 in the '118 application, which will issue on July 24, 2007; **Exhibit A**).

The present claims are based upon compositions in which the claimed antibody is defined in terms of the particular characteristics of the deposited 3G4 antibody. The allowed claims in the '118 application are drawn to compositions in which the claimed antibody is defined in terms of the particular CDR sequences of the deposited 3G4 antibody. Therefore, the present claims

and the claims allowed in the '118 application define antibodies in terms of the functional and structural characteristics of the deposited 3G4 antibody, respectively. As the same ELISA claims have been allowed in the '118 application, they clearly do not include new matter, and the present new matter rejection of the ELISA claims is thus improper and overcome based upon this evidence.

This is further strengthened by the fact that Examiner Goddard has already determined that the present claims are not patentably distinct from the claims allowed in the '118 application. This is evidenced by the double patenting rejection entered in the first Official Action in the present application (see also, Applicants' first response at Section VIII and terminal disclaimer of record). Therefore, as the ELISA claims have been allowed in the '118 application, and the present claims are drawn to an invention that is not patentably distinct from those allowed claims, then the present ELISA claims must also be allowed.

Accordingly, in addition to canceling the cofactor embodiments of claims 100, 108, 113 and 118, claims 1, 94, 97, 98 and 107 have each been revised to include the same ELISA language as allowed in the '118 application (this also imparts to all claims that depend from, or refer to, claim 1 or claim 97). The claimed antibodies thus have the particular characteristics of the deposited 3G4 antibody, as recited in the claims, which characteristics are determined in the ELISA that the specification disclosed for use in precisely such embodiments, *i.e.*, disclosed for use in identifying antibodies with the sought characteristics (see, *e.g.*, specification at page 6, lines 26-29, page 8, lines 22-24, page 12, lines 7-8, and at Example IV). The rejection is thus clearly overcome.

Other decisions of Examiner Goddard in additional co-pending applications further support the allowance of the ELISA claims. For example, in co-pending application Serial

No. 10/642,124 ("the '124 application"; Attorney Docket No. 3999.002984), the corresponding ELISA claims were identified as allowable (see third Official Action and claims 113, 114, 117, 118, 125, 126, 132 and 133 in the '124 application); and in co-pending application Serial No. 10/642,120 ("the '120 application"; Attorney Docket No. 4001.002900), the corresponding ELISA claims were also free from this ground of rejection (see third Official Action and claims 40, 41, 44, 45, 48, 49, 52, 53, 56 and 57 in the '120 application). Again, Examiner Goddard has determined that the present claims are not patentably distinct from the allowable and non-rejected claims in the '124 and '120 applications, as shown by the double patenting rejections of record in this application. Therefore, this is additional strong evidence from the Office itself supporting the allowance of the ELISA claims in the present application.

The new matter rejection under 35 U.S.C. § 112, first paragraph is thus overcome and should be withdrawn.

VI. Written Description Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 100, 108, 113 and 118 are next rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description support in the specification. Although Applicants respectfully traverse, the rejection is now moot.

Applicants appreciate the indication that each of the independent claims, including claims 1, 96, 97 and 98, and each of the ELISA claims, including claims 101, 109, 114 and 119, are free from this ground of rejection.

In light of the foregoing indication that many claims, including claims 101, 109, 114 and 119, are not subject to this rejection, and without acquiescing with the present rejection in any way, Applicants have elected to cancel claims 100, 108, 113 and 118, thus rendering the present rejection moot and overcome. This choice is in no way an acquiescence with the second

Action's position at pages 5-10, including the interpretation of the case law (both the cases cited and those omitted) and its connection with the present specification, including the deposit, and the prosecution history.

In any event, the written description rejection under 35 U.S.C. § 112, first paragraph is overcome and should be withdrawn.

VII. Rejection of Claim 95 Under 35 U.S.C. § 101

Claim 95 alone is rejected under 35 U.S.C. § 101, as allegedly being directed to non-statutory subject matter. The rejection is now moot.

The second Action takes the position that the invention of claim 95 is non-statutory subject matter as reading on an antibody that is found in nature (second Action at page 11).

Claim 95 is a product-by-process claim. The approaches used to assess product-by-process claims differ between the U.S. Patent and Trademark Office and the courts, including the Federal Circuit. There is substantial case law supporting the position that the antibody of claim 95 is limited by the process steps in the claim, including the "immunizing" step, thus clearly distinguishing claim 95 from non-statutory subject matter.

Nonetheless, in light of the scope of all pending claims, including claims 1, 23, 97, 99 and others, and without acquiescing with the present rejection in any way, Applicants have elected to cancel claim 95, thus rendering the present rejection moot and overcome. This choice is in no way an acquiescence with the second Action's position at page 11.

The rejection under 35 U.S.C. § 101 is thus overcome and should be withdrawn.

VIII. First Anticipation Rejection Under 35 U.S.C. § 102(b)

Claims 95 and 122 only are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Maneta-Peyret *et al.*, *J. Immunol. Methods*, 108:123-127, 1988 ("Maneta-Peyret"). Although Applicants respectfully traverse, the rejection is now moot.

The rejection is applied to claims reciting polyclonal antibodies that effectively compete with the deposited 3G4 antibody for binding to PS (second Action at pages 12-13), whether or not it is proper to exclude the process claim language of claim 95 **(Section VII)**.

In light of the scope of all pending claims, including claims 1, 23, 97, 99 and others, and without acquiescing with the present rejection in any way, Applicants have elected to cancel claim 95 and to revise claim 122, thus rendering the present rejection moot and overcome. This choice is in no way an acquiescence with the second Action's position at pages 12-13.

The first anticipation rejection under 35 U.S.C. § 102(b) is thus overcome and should be withdrawn.

IX. Second Anticipation Rejection Under 35 U.S.C. § 102(b)

Claims 1-6, 12, 23, 93-98, 101, 102, 109, 110, 114, 115, 119, 120 and 122 are further rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Rote *et al.*, *Clin. Immunol. Immunopathol.*, 66:193-200, 1993 ("Rote"). Although Applicants respectfully traverse, the rejection is overcome.

The rejection is based upon the "BA3" and 3SB" antibodies in Rote, which the Action alleges appear to be the same as the claimed antibodies, *i.e.*, would effectively compete with the 3G4 antibody for binding to PS (second Action at pages 14-15), whether or not it is proper to exclude process claim limitations **(Section VII)**.

The 3SB antibody does not effectively compete with the 3G4 antibody for binding to PS using an ELISA as recited in the claims. This is shown by data from a competitive binding ELISA, which are provided herewith in the form of the Third Declaration of Philip E. Thorpe under 37 C.F.R. § 1.132 ("the third Thorpe Declaration"). As shown in Exhibit B to the third Thorpe Declaration, using an ELISA competition study, there is no detectable reduction in the binding of 3G4 to PS in the presence of increasing amounts of 3SB (third Thorpe Declaration at paragraphs 6-9). Rather, 3G4 binding remains essentially constant at about 100%, very similar to the results using a control as a competing antibody (third Thorpe Declaration at paragraph 9; Exhibit B).

The 3SB antibody has thus been demonstrated not to compete with the 3G4 antibody for binding to PS. The BA3 and 3SB antibodies of Rote were generated using the same method, which is different to and lacks the advantages of the immunization techniques of the present invention. In particular, the 3G4 antibody of the present invention was generated by immunizing with activated endothelial cells, in which the membrane-exposed aminophospholipids and anionic phospholipids are surrounded by other membrane components. This contrasts to the artificial micelles and Freund's complete adjuvant used by Rote (see, *e.g.*, specification at Example IV, and page 19, lines 22-34). Although 3SB is a useful antibody, the 3G4 and competing antibodies developed by the present inventors nonetheless out-perform the 3SB antibody in comparative studies (see, *e.g.*, specification at page 66, lines 28-32; Example XIII).

Therefore, now that the 3SB antibody has been distinguished from the claimed invention, and as BA3 and 3SB were generated by the same prior art method, very different to the innovative method of the present invention, there is no basis for maintaining the same rejection over the BA3 antibody. The rejection should thus be withdrawn on these grounds.

Nonetheless, Applicants appreciate the indication that claims 9, 10, 11 and 107 are free from this ground of rejection and the other anticipation rejections (Action at pages 13-22). Moreover, Applicants appreciate that no claims, including claims 9, 10, 11 and 107, have been rejected under 35 U.S.C. § 103(a) as legally obvious over Rote or any other reference(s), either alone or in combination.

In light of these findings, and without acquiescing with the present rejection in any way, all claims have been clearly distinguished from the prior art by using the language already found to be novel and non-obvious in claims 9 and 10 and in claim 107, none of which are subject to prior art rejection[1]. Accordingly, claims 1, 94, 97 and 98 have each been revised to recite the language of claims 9 and 10, in the alternative (which also imparts to all claims that depend from, or refer to, claim 1 or claim 97), and claim 107 has been maintained[2].

The second anticipation rejection under 35 U.S.C. § 102(b) is therefore overcome and should be withdrawn.

X. Third Anticipation Rejection Under 35 U.S.C. § 102(b)

Claims 1, 2, 5, 12, 13, 23, 93-97, 101, 102, 109, 110, 114, 115, 119, 120 and 122 are also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Umeda *et al.*, *J. Immunol.*, 143:2273-2279, 1989 ("Umeda"). Although Applicants respectfully traverse, the rejection is overcome.

The rejection is based upon various antibodies in Umeda, which the Action alleges appear to be the same as the claimed antibodies, *i.e.*, would effectively compete with the 3G4

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[1]Given that claims 9, 10, 11 and 107 are not subject to prior art rejection(s), should the Office wish to enter further § 102(b) or § 103(a) rejection(s) against any pending claim, that would have to be part of a Non-Final Office Action, being a new ground of rejection not necessitated by Applicants' amendment or untimely submission of references.

[2]The ELISA language has been added to claim 107 as well as to claims 1, 94, 97 and 98, as addressed above (**Section V**).

antibody for binding to PS (second Action at pages 17-18), whether or not it is proper to exclude process claim limitations (**Section VII**).

The Umeda antibodies are shown to be distinguished from 3G4 and competing antibodies by reference to the present specification. Table 4 of the specification shows that the 3G4 antibody has the advantage of recognizing all or most anionic phospholipids, thus providing more targets for binding in therapeutic applications (and diagnostic and other binding embodiments) (see, *e.g.*, specification at Table 4, and page 66, lines 4-5). Thus, the Umeda antibodies PS4A7, PS1G3, PS3A, PSF6, PSF7, PSB4 and PS3H1 are distinguished from 3G4 and competing antibodies as they do not have the required cross-reactivity (Umeda at Table 1)

As to Umeda's cross-reactive antibodies, the binding profile of 3G4 and competing antibodies is different to that of PSC8 (specification at page 66, lines 1-2 *vs.* Umeda at Figure 3), and thus different to PS3D12, PSF11 and PSG3, which are similar to PSC8 (Umeda at page 2275, column 2, paragraph 1).

Most Umeda antibodies have thus been distinguished from 3G4 and competing antibodies. Moreover, each of the Umeda antibodies was generated using the significantly limited method of direct immunization of phosphatidylserine into mouse spleen using a *Salmonella*-coated aminophospholipid sample (Umeda at page 2274; specification at page 65, lines 30-34). The highly artificial Umeda method is clearly different to and lacks the advantages of the immunization techniques of the present invention, as described above (**Section IX**).

Therefore, now that most of the Umeda antibodies have been distinguished from the claimed invention, and as all Umeda antibodies were generated by the same, limited prior art method, very different to the innovative method of the present invention, there is no basis for

maintaining the present rejection. The present rejection should thus be withdrawn on these grounds.

Nonetheless, as set forth above, Applicants appreciate the indication that claims 9, 10, 11 and 107 are free from this ground of rejection and any other rejection on the basis of prior art (**Section IX**). Accordingly, and without acquiescing with the present rejection in any way, all claims have been clearly distinguished from the prior art by using the language already found to be novel and non-obvious in claims 9 and 10 and in claim 107, none of which are subject to prior art rejection[1]. Accordingly, claims 1, 94, 97 and 98 have each been revised to recite the language of claims 9 and 10, in the alternative (which also imparts to all claims that depend from, or refer to, claim 1 or claim 97), and claim 107 has been maintained[2].

The third anticipation rejection under 35 U.S.C. § 102(b) is therefore overcome and should be withdrawn.

XI. Fourth Anticipation Rejection Under 35 U.S.C. § 102(b)

Claims 1-8, 12-19, 51, 52, 93, 94, 96-98, 100-102, 108-110, 113-115, 118-120 and 122 are additionally rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by PCT publication WO 00/02584 by Thorpe and Ran. Although Applicants respectfully traverse, the rejection is overcome.

The rejection is based upon various antibodies in WO 00/02584, many of which are the same as in Rote and Umeda, which have been distinguished above (**Sections IX** and **X**). The Action alleges that any additional antibodies appear to be the same as the claimed antibodies, *i.e.*, would effectively compete with the 3G4 antibody for binding to PS (second Action at pages 21-22).

At the time of WO 00/02584, although anti-PS antibodies could be made, all the available techniques suffered from different drawbacks and limitations, such as those described above for the Rote and Umeda methods (also set forth in WO 00/02584 at pages 71-73). The prior art methods were all different to and lacked the advantages of the immunization techniques of the present invention (**Sections IX** and **X**), and would thus not be expected to produce antibodies with the desirable characteristics of 3G4.

Therefore, now that the Rote and Umeda antibodies have been distinguished from the claimed invention (**Sections IX** and **X**), and as all prior art antibodies were generated by the limited prior art methods, very different to the innovative method of the present invention, there is no basis for maintaining the present rejection, which should thus be withdrawn on these grounds.

Nonetheless, as set forth above, Applicants appreciate the indication that claims 9, 10, 11 and 107 are free from this ground of rejection and any other rejection on the basis of prior art (**Sections IX** and **X**). Accordingly, and without acquiescing with the present rejection in any way, all claims have been clearly distinguished from the prior art by using the language already found to be novel and non-obvious in claims 9 and 10 and in claim 107, none of which are subject to prior art rejection[1]. Accordingly, claims 1, 94, 97 and 98 have each been revised to recite the language of claims 9 and 10, in the alternative (which also imparts to all claims that depend from, or refer to, claim 1 or claim 97), and claim 107 has been maintained[2].

The fourth anticipation rejection under 35 U.S.C. § 102(b) is therefore overcome and should be withdrawn.

XII. Provisional Rejections for Obviousness-Type Double Patenting

Seven provisional rejections of claims 1-19, 23, 51, 52 and 93-122, *i.e.*, all pending claims, under the judicially created doctrine of obviousness-type double patenting are also set forth, as follows:

Over claims 1-37 of co-pending Application Serial No. 10/642,071 (Attorney Docket No. 4001.003083);

Over claims 1-36 and 39-57 of co-pending Application Serial No. 10/642,120 (Attorney Docket No. 4001.002900);

Over claims 1-34 of co-pending Application Serial No. 10/642,058 (Attorney Docket No. 4001.003084);

Over claims 1-31 of co-pending Application Serial No. 10/642,116 (Attorney Docket No. 4001.003087);

Over claims 1-55 of co-pending Application Serial No. 10/642,119 (Attorney Docket No. 3999.002983);

Over claims 1-23 of co-pending Application Serial No. 10/642,065 (Attorney Docket No. 3999.003089); and

Over claims 1-19 of co-pending Application Serial No. 10/620,850 (Attorney Docket No. 4001.003082).

Applicants do not necessarily agree with all the legal or scientific reasoning set forth. Nonetheless, in order progress the present application to issue as soon as possible, Applicants elect to overcome the rejections by filing the enclosed terminal disclaimer and fee.

The provisional rejections are therefore overcome and should be withdrawn.

XIII. Conclusion

This is a complete response to the referenced Official Action. In conclusion, Applicants submit that, in light of the foregoing remarks and accompanying documents, the present application is in condition for allowance and such favorable action is respectfully requested.

Should Examiner Goddard have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

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